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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: BONNAFFE, David et al.

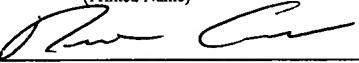
Title: GAMMA-INTERFERON-BINDING COMPOUNDS, PROCESS FOR PREPARING THEM, AND MEDICAMENTS CONTAINING THEM

Appl. No.: 10/518,177

Intl. Filing Date: 6/18/2003

Examiner: Not Yet Assigned

Art Unit: Not Yet Assigned

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Sir:

Transmitted herewith are the following documents for filing in the above-identified application.

1. First Information Disclosure Statement (3 pgs.);
2. PTO Form SB/08 (5 pgs.);
3. Fifty-nine (59) references as cited on Form SB/08 (B1 and C1-C58); and
4. Return postcard.

[X] The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any

overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date Mar 2 2005

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1105
Facsimile: (650) 856-3710

By Julie L. Heinrich
Julie L. Heinrich
Agent for Applicant
Registration No. 48,070



105-16101 04 MAR 2005

Atty. Dkt. No. 355901-0104

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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(Printed Name)


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FIRST INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to

antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the date of entry of the national stage as set forth in 37 CFR §1.491.

RELEVANCE OF EACH DOCUMENT

The relevance of the foreign-language document is described in the English Abstract provided in the PCT publication. An English translation of the foreign-language document is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language document (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

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By


Julie L. Heinrich
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Registration No. 48,070

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| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | Application Number | 10/518,177 |
| Date Submitted: March 2, 2005 | | Int'l Filing Date | 6/18/2003 |
| (Use as many sheets as necessary) | | First Named Inventor | David BONNAFFE |
| Sheet | 1 | Group Art Unit | Not Yet Assigned |
| | of | Examiner Name | Not Yet Assigned |
| | 5 | Attorney Docket Number | 355901-0104 |

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

NON-PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
|--------------------|-----------------------|--|----------------|
| | C1 | Lortat-Jacob et al. "Interferon-Gamma Binds to Heparan Sulfate by a Cluster of Amino Acids Located in the C-terminal Part of the Molecule" <i>FEBS LETTERS</i> 280(1):152-154 (1991) | |
| | C2 | Lortat-Jacob et al. "Non-receptor-Mediated Tissue Localization of Human Interferon-Gamma. Role of Heparan Sulfate/Heparin-Like Molecules" <i>Cytokine</i> 8(7):557-566 (1996) | |
| | C3 | Billiau, Alfons "Interferon-Gamma: Biology and Role in Pathogenesis" <i>Advances in Immunol.</i> 62:61-130 (1996) | |
| | C4 | Boutin et al. "Intrapleural Treatment with Recombinant Gamma-Interferon in Early Stage Malignant Pleural Mesothelioma" <i>Cancer</i> 74:2460-2467 (1994) | |

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| | | | Group Art Unit | Not Yet Assigned | |
| | | | Examiner Name | Not Yet Assigned | |
| | | | Attorney Docket Number | 355901-0104 | |

NON PATENT LITERATURE DOCUMENTS

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| | C5 | Escudier et al. "Combination of Interleukin-2 and Gamma Interferon in Metastatic renal Cell Carcinoma" <i>Eur. J. Cancer</i> 29A(5):724-728 (1993) | |
| | C6 | Jett et al. "Phase III Trial of Recombinant Interferon Gamma in Complete Responders with Small-Cell Lung Cancer" <i>J. Clin. Oncol.</i> 12(11):2321-2326 (1994) | |
| | C7 | Gallin, et al. "A Controlled Trial of Interferon Gamma to Prevent Infection in Chronic Granulomatous Disease" <i>New Engl. J. Med.</i> 324(8) 509-516 (1991) | |
| | C8 | Cannon et al. "Prospective 5-Year Followup of Recombinant Interferon-Gamma in Rheumatoid Arthritis" <i>J. Rheumatol.</i> 20:1867-1873 (1993) | |
| | C9 | Czarniecki et al. "Interferon-Gamma and Resistance to Bacterial Infections" <i>APMIS</i> 101:1-17 (1993) | |
| | C10 | Murray et al. "Interferon-Gamma and Host Antimicrobial Defense: Current and Future Clinical Applications" <i>Am. J. Med.</i> 97:459-467 (1994) | |
| | C11 | Kakumu et al. "Treatment with Human Gamma Interferon of Chronic Hepatitis B: Comparative Study with Alpha Interferon" <i>J. Med. Virol.</i> 35:32-37 (1991) | |
| | C12 | Freundlich et al. "Treatment of Systemic Sclerosis with Recombinant Interferon-Gamma" <i>Arthritis Rheum.</i> 35(10):1134-1142 (1992) | |
| | C13 | Todd et al. "Interferon Gamma-1b" <i>Drugs</i> 43(1):111-122 (1992) | |
| | C14 | Froyen et al. "Potential Therapeutic Use of Antibodies Directed Towards HuIFN-Gamma" <i>Biotherapy</i> 10:49-57 (1997) | |
| | C15 | Ozmen et al. "Soluble Interferon-Gamma Receptor: A Therapeutically Useful Drug for Systemic Lupus Erythematosus" <i>J. of Interferon Res.</i> 14:283-284 (1994) | |
| | C16 | Ozmen et al. "Experimental Therapy of Systemic Lupus Erythematosus: The Treatment of NZB/W Mice with Mouse Soluble Interferon-Gamma Receptor Inhibits the Onset of Glomerulonephritis" <i>Eur. J. Immunol.</i> 25:6-12 (1995) | |
| | C17 | Lortat-Jacob et al. "High-Affinity Binding of Interferon-Gamma to a basement Membrane Complex (Matrigel)" <i>J. Clin. Invest.</i> 87:878-883 (1991) | |
| | C18 | Lortat-Jacob et al. "Interferon-Gamma C-Terminal Function: New Working Hypothesis. Heparan Sulfate and Heparin, New Targets for IFN-Gamma, Protect, Relax The Cytokine and Regulate Its Activity" <i>Cell. Mol. Biol.</i> 37(3):253-260 (1991) | |
| | C19 | Lortat-Jacob et al. "Heparin Decreases the Blood Clearance of Interferon-Gamma and Increases its Activity by Limiting the Processing of its Carboxyl-terminal Sequence" <i>J. of Biol. Chem.</i> 271(27):16139-16143 (1996) | |

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| <p style="text-align: center;">O I P E</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>MAR 04 2005 Date Submitted: March 2, 2005 (use as many sheets as necessary)</p> <p>3 of 5</p> | | | <p style="text-align: center;"><i>10 NOV 2005 34 MAR 2005</i></p> <p>Complete if Known</p> <table border="1"> <tr> <td>Application Number</td> <td>10/518,177</td> </tr> <tr> <td>Int'l Filing Date</td> <td>6/18/2003</td> </tr> <tr> <td>First Named Inventor</td> <td>David BONNAFFE</td> </tr> <tr> <td>Group Art Unit</td> <td>Not Yet Assigned</td> </tr> <tr> <td>Examiner Name</td> <td>Not Yet Assigned</td> </tr> <tr> <td>Attorney Docket Number</td> <td>355901-0104</td> </tr> </table> | | Application Number | 10/518,177 | Int'l Filing Date | 6/18/2003 | First Named Inventor | David BONNAFFE | Group Art Unit | Not Yet Assigned | Examiner Name | Not Yet Assigned | Attorney Docket Number | 355901-0104 |
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| | C20 | Halme et al. "Inhaled Recombinant Interferon Gamma in Patients with Lung Cancer: Pharmacokinetics and Effects on Chemiluminescence Responses of Alveolar Macrophages and Peripheral Blood Neutrophils and Monocytes" <i>Int. J. Radiat. Oncol. Biol. Phys.</i> 31(1):93-101 (1995) | |
| | C21 | Lack et al. "Nebulized INFN-Gamma Inhibits the Development of Secondary Allergic Responses in Mice" <i>J. Immunol.</i> 157:1432-1439 (1996) | |
| | C22 | Short et al. "Percutaneous Absorption of Biologically-Active Interferon-gamma in a Human Skin Graft-Nude Mouse Model" <i>Pharm. Res.</i> 13(7):1020-1027 (1996) | |
| | C23 | Lortat-Jacob et al. "Molecular Organization of the Interferon Gamma-Binding Domain in Heparan Sulphate" <i>Biochem. J.</i> 310:497-505 (1995) | |
| | C24 | Lee, et al. "Synthesis of 3-(2-Aminoethylthio)Propyl Glycosides" <i>Carbohydrate Res.</i> 37:193-201 (1974) | |
| | C25 | Schmidt et al. "New Methods for the Synthesis of Glycosides and Oligosaccharides – Are There Alternatives to the Koenigs-Knorr Method?" <i>Agnew Chem. Int. Ed. Engl.</i> 25:212-235 (1986) | |
| | C26 | Klotz et al. "Anomeric O-Alkylation of O-Unprotected Hexoses and Pentoses – Convenient Synthesis of Decyl, Benzyl, and Allyl Glycosides" <i>Liebigs. Ann. Chem.</i> 683-690 (1993) | |
| | C27 | Klotz et al. "Anomeric O-Alkylation of O-Acetyl-Protected Sugars" <i>J. Carbohydrate Chemistry</i> 13(8):1093-1101 (1994) | |
| | C28 | Terjung et al. "New 2/2-Type Surfactants Via Anomeric O-Alkylation of Mannofuranose" <i>Carbohydr. Res.</i> 297:229-242 (1997) | |
| | C29 | Lubineau et al. "Syntheses of α -Linked Derivatives of N-Acetyl Glucosamine and Gal- β (1-3)GalNAc (T Antigen) Directly with the Natural N-Acetyl Protecting Group" <i>J. Chem. Soc. Chem. Commun.</i> 1918-1919 (1989) | |
| | C30 | Lubineau et al. "Stereoselectivity Control in Anomeric O-Alkylation. Application to the Synthesis of C ₂ Symmetric Glycoconjugates" <i>Tetrahedron Letters</i> 38(23):4087-4090 (1997) | |
| | C31 | Sakai et al. "Synthesis of a Conformationally Constrained Heparin-Like Pentasaccharide" <i>Chem. Eur. J.</i> 2(8):1007-1013 (1996) | |
| | C32 | Petitou et al. "A Synthetic Heparin/Heparan Sulfate-Like Decasaccharide Releases Lipase Activity <i>In Vivo</i> . Chemical Synthesis and Biological Activity" <i>Bioorg. Med. Chem. Lett.</i> 7(15):2067-2070 (1997) | |
| | C33 | Petitou et al. "First Synthetic Carbohydrates with the Full Anticoagulant Properties of Heparin" <i>Agnew. Chem. Int. Ed.</i> 37(21):3009-3014 | |
| | C34 | Lei et al. "Synthesis of a 3-Deoxy-L-Iduronic Acid Containing Heparin Pentasaccharide to Probe the Conformation of the Antithrombin III Binding Sequence" <i>Boorgan. & Med. Chem.</i> 6:1337-1346 (1998) | |

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| | C35 | Basten et al. "In Vitro Evaluation of Synthetic Heparin-Like Conjugates Comprising different Thrombin Binding Domains" <i>Bioorg. Med. Chem. Lett.</i> 8:1201-1206 (1998) | | |
| | C36 | Duchaussoy et al. "Identification of a Hexasaccharide Sequence Able to Inhibit Thrombin and Suitable for 'Polymerisation'" <i>Carbo. Res.</i> 317:63-84 (1999) | | |
| | C37 | Duchaussoy et al. "Assessment Through Chemical Synthesis of the Size of the Heparin Sequence Involved in Thrombin Inhibition" <i>Carbo. Res.</i> 317:85-99 (1999) | | |
| | C38 | Koshida et al. "Synthesis of Heparin Partial Structures and their Binding Activities to Plateletes" <i>Bioor. Med. Chem. Lett.</i> 9:3127-3132 (1999) | | |
| | C39 | Kovensky et al. "A Synthetic Heparin Sulfate Pentasaccharide, Exclusively Containing L-Iduronic Acid, Displays Higher Affinity for FGF-2 than its D-Glucuronic Acid-Containing Isomers" <i>Bioor. & Med. Chem.</i> 7:1567-1580 (1999) | | |
| | C40 | La Ferla et al. "Synthesis of Disaccharide Sub-Units of a New Series of Heparin Related Oligosaccharides" <i>Tetrahedron</i> 55:9867-9880 (1999) | | |
| | C41 | Lubineau et al. "New Accesses to L-Iduronyl Synthons" <i>Tetrahedron Lett.</i> 41:307-311 (2000) | | |
| | C42 | Macher et al. "Synthesis of L-Idofuranuro-6,3-Lactone and Its Derivatives via Hexodialdofuranoses" <i>Carbo. Res.</i> 80:45-51 (1980) | | |
| | C43 | Jacquinet et al. "Synthesis of Heparin Fragments. A Chemical Synthesis of the Trisaccharide α -(2-Deoxy-2-Sulfamido-3,6-Di-O-Sulfo- α -D-Glucopyranosyl), etc." <i>Carbo. Res.</i> 130:221-241 (1984) | | |
| | C44 | Baggett et al. "Re-examination of the acid hydrolysis of 5,6-Anhydro-1,2-O-Isopropylidene- β -L-Idofuranose" <i>Carbo. Res.</i> 127:149-153 (1984) | | |
| | C45 | Medakovic et al. "An Efficient Synthesis of Methyl 1,2,3,4-tetra-O-acetyl- β -L-Idopyranuronate" <i>Carbo. Res.</i> 253:299-300 (1994) | | |
| | C46 | Dromowicz et al. "A Convenient Synthesis of D-Idose" <i>Carbo. Res.</i> 308:169-171 (1998) | | |
| | C47 | Hinou et al. "Novel Synthesis of L-Iduronic Acid Using Trehalose as the Disaccharide Starting Material" <i>Tetrahedron Lett.</i> 40:1501-1504 (1999) | | |
| | C48 | Adinolfi et al. "Intramolecular Tishchenko Reactions of Protected Hexos-5-Uloses: a Novel and Efficient Synthesis of L-Idose and L-Altrose" <i>Synlett</i> 3:336-338 (1999) | | |
| | C49 | Ojeda et al. "A New Route to L-Iduronate Building-blocks for the Synthesis of Heparin-like Oligosaccharides" <i>Synlett</i> 8:1316-1318 (1999) | | |

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| | | | Examiner Name | Not Yet Assigned | |
| | | | Attorney Docket Number | 355901-0104 | |

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| | C50 | Takahashi et al. "A Novel and Practical Synthesis of L-Hexoses from D-Glycono-1,5-Lactones" <i>J. Am. Chem. Soc.</i> 122:2995-3000 (2000) | | |
| | C51 | Horton et al. "Ethynylation of 1,2-O-Isopropylidene- α -D-xylo-Pentadialdose derivatives. A Synthetic Route to Uronic Acids" <i>Carbo. Res.</i> 14:159-171 (1970) | | |
| | C52 | Danishefsky et al. "On the Communication of Chirality from Furanose and Pyranose Rings to Monosaccharide Side Chains: Anomalous Results in the Glucose Series" <i>Tetrahedron</i> 42(11):2809-2819 (1986) | | |
| | C53 | Vasella et al. "194. Convenient Synthesis of 2-Azido-2-deoxy-aldoses by Diazo Transfer" <i>Helvetica Chemica Acta.</i> 74:2073-2077 (1991) | | |
| | C54 | Alper et al. "Metal Catalyzed Diazo transfer for the Synthesis of Azides from Amines" <i>Tetrahedron Lett.</i> 37(34):6029-6032 (1996) | | |
| | C55 | Tabe et al. "Oligosaccharides Corresponding to the Regular Sequence of Heparin: Chemical Synthesis and Interaction with FGF-1" <i>Bioorg. & Medic. Chem.</i> 7:2003-2012 (1999) | | |
| | C56 | Oltvoort et al. "Use of the Cationic Iridium Complex 1,5-Cyclooctadiene-bis[methyldiphenylphosphine]-iridium Hexafluorophosphate in Carbohydrate Chemistry: Smooth Isomerization of Allyl Ethers to 1-Propenyl Esters" <i>Synthesis</i> 305-308 (1981) | | |
| | C57 | Dianzani F. "Interferon Treatments: How to Use an Endogenous System as a Therapeutic Agent" <i>J. of Interferon Res.</i> Special Issue May 1992, pp 109-118 | | |
| | C58 | Horton et al. "Preparation of Derivatives of L-Idose and L-Iduronic Acid from 1,2-O-Isopropylidene- α -D-Glucofuranose by Way of Acetylnic Intermediates" <i>Carbo. Res.</i> 58:89-108 (1977) | | |
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